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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/809,158 | 03/15/2001 | Carol O. Cowing | LANCELL.002CPI | 5364 |

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/809,158

Applicant(s)
Cowing

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 15, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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1. Claims 1-57 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-14, 18-24, 27-47, 51-57 are drawn to a method for vaccinating a mammal against an antigen comprising administering an antigen and a lipophilic molecule classified in Class 424, subclass 130.1+. It is noted that claim 1 is drawn to an improper implied Markush group involving treatments which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Group II. Claims 1-2, 15-16 and 18-24, 27-31, 48-49 are drawn to a method for vaccinating a mammal against an antigen comprising administering an antigen and a lipophilic molecule and an organic solvent

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classified in Class 424, subclass 130.1+. It is noted that claim 1 is drawn to an improper implied Markush group involving treatments which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Group III. Claims 1 and 17-24, 27-31, 50, 55, 57 are drawn to a method for vaccinating a mammal against an antigen comprising administering an antigen and a ultrasound energy classified in Class 424, subclass 130.1+. It is noted that claim 1 is drawn to an improper implied Markush group involving treatments which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Group IV. Claims 1 and 25-31 are drawn to a method for vaccinating a mammal against an antigen comprising administering an antigen and a topical treatment whereby the antigen is introduced by transforming a cell within the mammal classified in Class 514, subclass 44. It is noted that claim 1 is drawn to an improper implied Markush group involving treatments which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-I are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claims 1 and 32 are generic to a plurality of disclosed patentably distinct species comprising lipophilic molecules with different structures and functions wherein the antigens are recited in (a) Claims 3/36(1), (b) Claim 3/36(2), © Claim 3/36(3), wherein each of the antigens is an antigen with a plethora of different structures and therefore functions as recited in claims 3-11, 36-44. Applicant is required to elect a single species, either (1), (2) or (3) with each of the R, W and X groups are groups specifically defined and wherein Applicant specifically designates a ring group or non-ring group structure, wherein the lipophilic molecule is defined (as per claims 10-11 if those claims are drawn to the elected species). The dependent claims in the group will be examined as they are drawn to the elected species.

6. Groups I-III are further subject to election of a single disclosed species.

Claims 1 and 32 are generic to a plurality of disclosed patentably distinct species comprising methods of introducing the antigen or epitopes thereof into the mammal recited in claims 18-24, 54-56 wherein the methods are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Applicant is required to elect a single method of introduction for examination.

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7. Groups I-IV are further subject to election of a single disclosed species.

Claim 1 are generic to a plurality of disclosed patentably distinct species comprising antigens or epitopes thereof with different structures and functions wherein the antigen is (a) normal, (b) pathologic, both of claim 27.

8. Groups I-IV are further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising methods wherein the topical treatment has different effects on function wherein the effects are those recited in claims 28-31. Applicant is required to elect a single specific effect for examination.

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter

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of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention

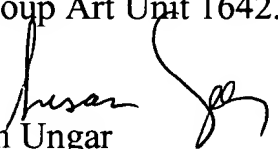
12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar

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Primary Patent Examiner
April 5, 2002



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

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